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Section 5: 510(k) Summary

The Summary of Safety and Effectiveness on the GluStitch, Inc. GluSeal® 90 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Don Blacklock GluStitch, Inc. 7188 Progress Way, #307 Delta, British Columbia Canada V4G 1M6 FEB 23 2009
Telephone **Facsimile**	800-667-2130 877-450-4000
Date	December 18, 2008
Name	GluSeal® 90
Classification	Liquid Bandage, 21 CFR 880.5090
Predicate:	• K063202 Procurement Technology Systems, LLC, ProDerma, market clearance date May 2, 2007; and • K002338 Closure Medical Corporation's Liquiderm™ Liquid Adhesive Bandage, market clearance date January 29, 2001.
Description:	The GluSeal® 90 is a formulated compound of the cyanoacrylate series. The compound, which exists in monomeric form in the plastic containers, polymerizes extremely rapidly in the presence of anions, especially of hydroxyl ions [in the presence of water]. It has the ability to adhere to moist living tissues. It demonstrates a favorable tissue response and reveals no toxic or foreign body reaction in humans.
Intended Use	GluSeal® 90 liquid adhesive bandage is intended to cover minor cuts, scrapes, burns, and minor irritations of the skin and help protect them from infection.
Contraindication:	Do not apply GluSeal® 90 adhesive to the eye(s). If contact with the eye(s) occurs, keep the eye(s) closed and covered, and immediately contact an ophthalmologist. No attempt should be made to open the eye(s). The adhesive will lose its adhesion over time, between one and four days and the eye(s) will open spontaneously with no damage. Do not use on infected areas, or wounds that are draining.
Warning	Do not use on mucosal surfaces (e.g., oral cavity, lips). Do not use if hypersensitive to cyanoacrylate.
Technological Characteristics	When applied on a wound, the GluSeal® 90 product polymerizes to form a thin, protective film, within less than a minute. The applied GluSeal® 90 has a high degree of adhesion strength. The GluSeal® 90 film remains adhered to the tissue surface until the underlying tissue is sloughed through natural re-epithelialization or until mechanically displaced.

510k) Summary continue K083752

The Summary of Safety and Effectiveness on the GluStitch, Inc. GluSeal® 90 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Performance Testing	The Hydrolytic Byproducts Analyses indicated that no other significant degradation products were produced in the GluSeal® 90 formulated cyanoacrylate. Additionally, the GluSeal® 90 samples produced similar levels of formaldehyde as found in the Indermil samples. The Thermal Effects Study concluded that the GluSeal® 90 had very little exotherm of the adhesive. Furthermore, the GluSeal® 90 performed similarly to the control article Indermil during these tests. The Adhesive Strength Properties Study concluded that the GluSeal® 90 appears to have similar properties to the Indermil commercial tissue adhesive
Substantial Equivalency Information	The GluSeal® 90 formulation has been subjected to the appropriate biocompatibility testing in accordance with ANSI/AAMI/ISO 10993 and the results have confirmed that the product is safe for its intended use. GluSeal® 90 has also been subjected to mechanical and performance tests demonstrating equivalence to the predicated devices.
Conclusion	Testing as shown that the GluSeal® 90 performs to its specifications, operates as intended, is safe and effective, and is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2009

GluStitch, Inc.
% Mr. Don Blacklock
President
307-7188 Progress Way
Delta, British Columbia V4G 1M6
Canada

Re: K083752
Trade/Device Name: GluSeal® 90
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: December 17, 2008
Received: December 17, 2008

Dear Mr. Blacklock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K083752

Device Name: GluSeal® 90

Indications For Use:

GluSeal® 90 liquid adhesive bandage is intended to cover minor cuts, scrapes, burns, and minor irritations of the skin and help protect them from infection.

Prescription Use _____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Res
and Neurological Device

510(k) Number K083752